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PATENT

IN THE UNITED STATES PATENT & TRADEMARK OFFICE

Applicant: Sandor Sipka et al

Serial No.: 10/651,136

Group Art Unit: 1644

Filed: August 28, 2003

Examiner: Rooney, Nora Maureen

For: Processes For Inhibiting Development of Allergic Disease

Mail Stop AF
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

DECLARATION UNDER 37 C.F.R. 1.132

Dear Sir:

Dr. Lóránd Bertók declares that:

1. He was awarded a Doctor of Veterinary Medicine in 1957 from the University of Veterinary Medicine in Budapest, Hungary; a Doctor of Philosophy for Immunology, Microbiology Comparative-Pathophysiology in 1965 from the Hungarian Academy of Science in Budapest, Hungary; a Doctor of Medicine and Doctor of Science for Immunology and Radiobiology in 1984 from the Hungarian Academy of Science in Budapest, Hungary; and a Medical Habil Degree in Medical Immunology in 1995 from Semmelweis Medical University in Budapest, Hungary. Over the course of his career he has served numerous appointments and positions, including, Chief Scientific Councilor, National Center of Public Health "Frédéric Joliot-Curie" National Research Institute for Radiobiology and Radiohygiene; Professor, Department of Microbiology at Semmelweis Medical University in Budapest, Hungary; Advisory of Rector Magnificus at Semmelweis Medical University in Budapest, Hungary; Vice President of Animal Protection Advisory Board and Animal Experimental Ethic Committee of

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Agricultural Ministry; President of Animal Experimental Scientific Interdisciplinary Committee of the Hungarian Academy of Sciences; Founder Member of the Hungarian Immunological Society; and Founder Member of the International Endotoxin Society. Over the course of his career, he has published more than 250 scientific original articles, reviews and additional publications relating to immunology (a list of publications is attached). Over the course of his career, he has been decorated with numerous distinguished awards, including, Distinguished Research Worker (1960, 1961, 1964, 1968 Ministry of Education/Ministry of Health); Academic Price (1963, 1985 Hungarian Academy of Science); Silver Medal of Work (1978 Presidium of the Hungarian Republic); Excellent Worker (1987 Ministry of Health); International Man of the Year (Medicine) (1993-1994 Cambridge, England); Twentieth Century Achievement Award (1995 Raleigh, North Carolina); inducted into the Hall of Fame of Medicine (1995 Raleigh, North Carolina); "Markusovazky Award" of the Hungarian Medical Journal (1999); "Széchenyi Award" (2002, the highest scientific decoration of the Presidium of the Hungarian Republic); Medal of the President (2005 Hungarian Republic), and "Pro Universitate et Scientia" Medal (2005 World Committee of the Hungarian Professors).

2. He is a co-inventor of and familiar with the present application Serial No. 10/651,136 filed on August 28, 2003, is familiar with the Official Action dated October 23, 2006, and the references cited therein, specifically, Tulic et al, *Am. J. Resp. Cell Mol. Biol.*, Vol. 22, pp. 604-612, 2000, Matricardi et al, "Microbial Products in Allergy Prevention and Therapy", *Allergy*, 2003:58:pp. 461-471, Bertók, "Stimulation of Nonspecific Resistance By Radiation-Detoxified Endotoxin", *Beneficial Effects of Endotoxins*, Plenum Publishing Corp., 1983, pp. 213-226 and Liu et al, *Current Reviews of Allergy and Clinical Immunology*, Vol. 109, pp. 379-392, 2002.

3. In response to the comments set forth by the Examiner in the Official Action dated October 23, 2006, he declares, based on his experience in the medical and research fields, and particularly the field of immunology, it is his opinion that there is no teaching, suggestion or reference in the cited Bertók reference to use irradiation detoxified LPS to inhibit the development of allergic disease in a neonatal or immature mammal or bird. Specifically, based on his extensive experience in the field of immunology, it is his opinion the use of irradiation detoxified LPS to induce a nonspecific resistance for the pretreatment of various shocks,

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radiation disease and infections does not teach, suggest or recognize the use of irradiation detoxified LPS to stimulate a specific response to inhibit the development of allergic disease in a neonatal or immature mammal or bird. Moreover, it is his opinion that there would be no motivation to look to the teachings of the Bertók reference to inhibit the development of allergic disease in a neonatal or immature mammal or bird because the Bertók reference is directed to the stimulation of a nonspecific resistance, which the claimed processes of the present invention induce a specific resistance to stimulate a Th-1 immune response to inhibit the development of allergic disease in a neonatal or immature mammal or bird as required by the claims of the present invention. One of ordinary skill in the art would, in his opinion, have no expectation that a pathogen providing the nonspecific resistance taught by the Bertók reference would be suitable for providing a different, specific resistance to inhibit the development of allergic disease in a neonatal or immature mammal or bird. Accordingly, based on his experience, it is his opinion that there would be no teaching, suggestion or motivation to combine the Bertók reference with the other cited references because the Bertók reference specifically teaches the use of irradiation detoxified endotoxin to induce an elevated nonspecific resistance for the pretreatment of various shocks, radiation disease and infections.

4. He also declares, based on his experience that Tulic et al, Matricardi et al and Liu et al do not teach, suggest or recognize the use of irradiation detoxified LPS in a neonatal or immature mammal or bird for inhibiting the development of allergic disease. Moreover, it is his opinion, that there would be no motivation to look to the teachings of Tulic et al, Matricardi et al and Liu et al to inhibit the development of allergic disease by exposing a neonatal or immature mammal or bird to irradiation detoxified LPS.

5. He further declares that all statements made herein of his own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

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Respectfully Submitted,

February 6, 2007

Date

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Lóránd Bertók, DVM, Ph.D., MD/DSc, Med. Habil

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